

U. S. Food and Drug Administration
Dockets Management Branch (HFA-305)
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

November 17, 1997

Docket No. 97N-0451

4873 '97 NOV 19 A9:21

Sirs,

I unable to participate in the public meeting on "Microbial Safety of Produce" being held on November 17, 1997. To provide my input to this important and complicated initiative, I am sending these written comments for the docket.

Rising numbers of incidents of illness associated with food is not only an issue in the United States. It is an issue around the world and I submit that the approach to be successful in dealing with the problem needs to be taken worldwide. Increasing international trade makes a global approach necessary. This meeting is a first step being taken by the U.S. and is needed to set the stage for a global approach. However, before going to the World Health Organization/Food and Agriculture Organization/Codex Alimentarius, it may be prudent to ensure that the U.S. Agencies are united in their positions and policies. For this reason, I recommend that the Agencies who are hosting the November 17 meeting consider enrolling the U.S. Department of State, U.S. Trade Representative, and Agency for International Development in discussions of options available and resources that can be pooled to address the issues and approaches.

Following subsequent public meetings to establish consensus on the approach, we should enroll other countries with similar problems. For example, Great Britain is undergoing a crisis in food safety which has resulted in a major evaluation of its food safety/industry services agency and how to separate industry services from food safety as a result of rising incidents of foodborne illness. Also, Canada has been experiencing similar issues and is viewing optional approaches to the problems. Other countries rely on produce for currency and have an interest in the approaches being discussed. Discussions with all of those interested countries may provide a basis for a global approach more likely to succeed than one presented by the U.S. alone.

Regarding the issues (Good Agricultural Practices and Good Manufacturing Practices for fruits and vegetables) posed for comment in the Federal Register Notice of November 10, 1997, I provide the following comments on the approach to use in considering, creating, and implementing such initiatives:

1. The approach needs be from field to table. All segments of the chain of growers through consumption need to be addressed. This includes growers, producers/packers/processors, carriers, wholesalers, retailers, preparers, and consumers. The approach should be not only by regulation and regulators. It should include educators addressing all segments and also industry advisors.
2. The approach needs to be preventive. At each segment of the chain, an analysis of the sources and types of contamination needs to be conducted. For fruits and vegetables this would start on the farm and include sources and types of fertilizers and water and the condition of the soils. The presence of animals or runoff from their pastures may also be addressed.

Potential sources of microbial contamination would need be addressed at each segment. For example the containers used to transport produce should be clean and suitable for that purpose and packing materials used to prevent bruising of produce should not provide sources of contamination. Also, appropriate temperature controls may be considered to prevent growth of microorganisms. Preventive measures should also include worker health checks.

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3. For each segment, where contamination is found to be likely, preventive measures need to be set in place. These preventive measures should take all forms including education, technical assistance, and monitoring by authorities in the source country and on entry into the importing country. Monitoring by the source country may include observation to assure that the preventive activities are in place and are operational. Further verification of the program may include sampling to provide initial confidence in the program which can be decreased to an infrequent sample to periodically show the preventive measures are effective. A global approach is necessary and will have more chance to be effective with the cooperation of all involved U.S. agencies and interested countries.

4. Research is needed to provide the needed technical assistance and educational activities. Also, because some of the pathogens at issue are emerging and/or resistant to conventional therapies, research is needed to determine how to prevent such pathogens from becoming food contaminants that cause foodborne illness. For example, research into means of cleansing the produce or the use of ionizing radiation or chemical baths or heat to reduce or eliminate the contamination may be appropriate topics.

Thank you for the opportunity to provide my comments. Should any questions, workgroups, or issues arise that I may be of assistance on, please do not hesitate to call on me.

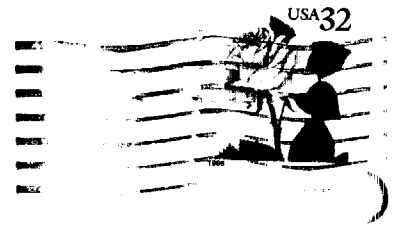
Sincerely,

A handwritten signature in black ink that reads "Richard Dees". The signature is fluid and cursive, with the first name "Richard" and last name "Dees" clearly legible.

Richard Dees

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